4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 172 and 182

[Docket Nos. FDA-2013-F-0700 and FDA-2013-P-0472]

Richard C. Theuer; Filing of Food Additive Petition and Citizen Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that Richard C. Theuer, Ph.D., has filed a petition proposing that the food additive regulations be amended to prohibit the use of carrageenan and salts of carrageenan in infant formula. In addition, the petitioner has submitted a citizen petition, under FDA regulations, requesting that we amend the generally recognized as safe (GRAS) regulations to prohibit the use of Chondrus extract (carrageenin) in infant formula.

FOR FURTHER INFORMATION CONTACT: Molly A. Harry, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1075.

SUPPLEMENTARY INFORMATION: Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(b)(5)), we are giving notice that Richard C. Theuer, Ph.D., 7904 Sutterton Ct., Raleigh, NC 27615, has filed a food additive petition (FAP 3A4798; Docket No. FDA-2013-F-0700). The petition proposes to amend the food additive regulations in 21 CFR 172.620 and 172.626 to prohibit the use of carrageenan and salts of carrageenan in infant formula. In addition, Dr. Theuer has submitted a citizen petition, under 21

CFR 10.30, requesting that 21 CFR 182.7255 of the GRAS regulations be amended to prohibit the use of Chondrus extract (carrageenin) in infant formula (Docket No. FDA-2013-P-0472). (Carrageenin is an alternate name for carrageenan.)

Although the petitioner has submitted both a food additive petition and a citizen petition, for reasons of administrative efficiency, we may address all aspects of the petitions under the procedures established in section 409 of the FD&C Act and regulations issued under that section.

We have determined under 21 CFR 25.32(m) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: July 16, 2013.

Dennis M. Keefe,

Director,

Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.

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